GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:435
ANSWERED ON:18.07.2017
GMP Norms
Bhatt Smt.Ranjanben

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether the Government has given any instruction to the pharmaceutical companies to comply with Good Manufacturing Practice (GMP) norms;

(b) if so, whether the GMP norms is not being followed so far;

(c) if so, whether the Government proposes to take any concrete steps to ensure its implementation; and

(d) if so, the time by which it is likely to be implemented?

Answer

MINISTER OF STATE IN THE MINISTRY OF ROAD TRANSPORT AND HIGHWAYS; MINISTRY OF SHIPPING AND MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI MANSUKH L. MANDAVIYA)

(a) to (d): Manufacture, sale and distribution of drugs are regulated under provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 through a system of Licencing and inspection. Licence for manufacturing, sale & distribution of drugs are granted by the State Licencing Authorities appointed by respective State Governments. The existing regulatory provisions require the drug manufacturer to comply with all the conditions of license, which include compliance with Good Manufacturing Practices (GMP) as prescribed under Schedule 'M' of the said Rules, to ensure that the drugs manufactured by them are of standard quality. State Licensing Authorities are empowered to take action on violation of any conditions of such Licenses.

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